

**K113374 ACE ALBUMIN REAGENT ACE TOTAL PROTEIN
REAGENT ACE CALCIUM-ARSENZO REAGENT ACE
PHOSPHORUS U.V. REAGENT**Jul 13, 2012
240 days to decisionK113374 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k113374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	Nov 16, 2011
Decision date	Jul 13, 2012
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann Diagnostic Technologies, Inc.
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	21 submissions · 21 cleared · 2008-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113374/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026